

REMARKS

Claims 1-16 are pending. Claims 10-16 are allowed. Claims 1-9 are rejected. Claim 17 has been added. Claim 5 has been canceled.

Claims 1-4 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 4,388,076 to Waters. Applicant traverses the rejection.

Waters describes a stylet 24 having a steel wire body 26, the distal end 28 of which is formed into a hook or ball 32. Col. 2, lines 15-27. The proximal end 32 of the wire 26 is formed into a hook 32, which engages the inside wall 34 of a hollow plug 36 that has been placed inside a connector 38. Col. 2, lines 15-30. The stylet 24 does not comprise a wire 26 that is connected to and integral with the distal end of the connector 38. Rather, the wire 26 is formed into a hook (FIG. 4), which engages the inside wall of a plug 36 inside connector 38. Col. 2, lines 15-20. The wire 26 is not integral with, i.e. does not form a single unit with, the connector 38.

Claim 1, as amended, is directed to an endotracheal tube retainer comprising "a solid semi-rigid stylet rod having proximal and distal ends, said stylet rod having a base portion at the distal end of the rod integral with said distal end; and a connection adapter tapered from a proximal end of said connection adapter to a distal end of said connection adapter for secure insertion within a range of endo-tracheal tubes, said adapter being connected to and integral with said base portion of the distal end of said solid stylet rod, wherein the endotracheal tube retainer is adapted to allow a sufficient amount of force to be exerted through the stylet rod and connection adapter on the endotracheal tube to resist withdrawal of the endotracheal tube from the laryngeal opening."

Waters does not anticipate amended claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Here it is clear that each and every element of claim 1 is not set forth in Waters. Claim 1 is directed to an endotracheal tube retainer that comprises a solid, semi-rigid stylet rod that is integral with, and connected at its distal end to a connection adapter. With reference to Figure 4 of Waters, Waters does not describe a device that comprises a connection adapter that is integral with the distal end of a stylet rod. The wire 26 described in Waters engages the inside wall 34 of a hollow plug 36 that has been placed inside of a connector 38. Since Waters fails to describe the endotracheal tube retainer of amended claim 1, it is respectfully submitted that claim 1 is not anticipated by Waters.

In addition, the claimed endotracheal tube retainer must be adapted to allow a sufficient amount of force to be exerted through the stylet rod and connection adapter to resist the tendency of the endotracheal tube to withdraw from the laryngeal opening. It is submitted that the wire 26 of Waters lacks the structural integrity to allow a sufficient amount of force to be exerted therethrough to resist the tendency of the endotracheal tube to withdraw from the laryngeal opening. First, the wire 26 is not integrally connected to the stylet 26. Second, the wire 26 is clearly too thin to be capable of allowing enough force to be exerted therethrough to prevent withdrawal of the tube. Therefore, Applicant requests that the rejection of amended claim 1 under 35 U.S.C. §102 (b) be withdrawn.

Claims 2-6 depend from amended claim 1, and therefore, incorporate all of the subject matter of therein. Since it is submitted for the aforementioned reasons that amended claim 1 is

patentable over Waters, it is likewise submitted that Claims 2-6 are patentable over Waters for the same reasons. Therefore, it is respectfully requested that the rejection of Claims 2-6 under 35 U.S.C. §102(b) be likewise withdrawn.

Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Waters. Claim 5 has been canceled.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 4,582,056 to McCorkle Jr. Applicant traverses the rejection.

McCorkle Jr. describes an endocardial lead extraction device that comprises flexible stainless steel stylet wires 9A that are connected to a screw tip 33. Col. 7, lines 40-44; Col. 8, lines 7-16. The wires 9A are adapted to fit within the inner channel 14 of the catheter 1, which is of slightly larger outside diameter than the insulating sheath of the endocardial lead 11 that is to be removed. Figure 1 and 3; Col. 8, lines 7-33; and Figures 8A-8C. The screw-tip 33 that is attached to the end of the stylet wire 9A is adapted to engage the free end of the endocardial lead 11 that is to be removed to draw it into the chamber 14 of the catheter 1. McCorkle Jr. does not describe an *endo-tracheal tube* retainer that comprises a semi-rigid stylet rod that is secured to a connection adapter.

McCorkle Jr. does not anticipate claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Here, it is clear that each and every element is not set forth in McCorkle Jr. First, claim 1 is directed to an endotracheal tube retainer that comprises a solid, semi-rigid stylet rod and a connection adapter that are integrally connected to each other. In addition, the adapter

and stylet are adapted to allow a sufficient amount of force to be exerted thereon to resist withdrawal of the endotracheal tube from the laryngeal opening. McCorkle Jr. describes an endocardial lead extraction device that comprises stylet wires 9A that are connected to a screw tip 33. Col. 7, lines 40-44; Col. 8, lines 7-16; and Figures 8A-8C. The parts are not integral. The screw-tip 33 that is attached to the end of the stylet wires 9A is adapted to engage the free end of the endocardial lead 11 that is to be removed to draw it into the chamber 14 of the catheter 1. Col. 8, lines 7-21. The stylet wires 9A of McCorkle are inherently too small to act as endotracheal tube retaining elements, i.e. to allow a sufficient amount of force to be exerted through the stylet rod and connection adapter on the endotracheal tube to resist withdrawal of the endotracheal tube from the laryngeal opening. Endotracheal leads are less than 2-3 millimeters in diameter. The wires 9A are adapted to fit within the inner channel 14 of a catheter 1, which is of slightly larger outside diameter than the insulating sheath of the endocardial lead 11 that is to be removed. Figure 1 and 3; Col. 8, lines 7-33. With specific reference to Figures 8A-8C, the screw-tip 33 described must have a diameter that is less than about 2-3 millimeters in order to facilitate engagement with the endocardial lead 11 that is to be removed. Figures 8A-8C. The stylet wires 9A, therefore, must inherently be smaller than about 2-3 millimeters to allow engagement and removal of the lead 11. The rod of the invention is inherently larger than the stylet wires 9A described in McCorkle because standard endotracheal tubes have diameters that are much greater than the diameters of endocardial leads. In fact use of the stylet wires 9A in the retainer of the invention would render the claimed invention inoperable. The stylet wires 9A are simply too small to engage even the smallest endotracheal tubes and to allow a sufficient amount

of force to be asserted thereon to resist withdrawal of an endotracheal tube from a laryngeal opening.

Since McCorkle Jr. fails to describe the claimed endotracheal tube retainer, it is respectfully submitted that amended claim 1 is not anticipated by McCorkle Jr. Therefore, Applicant requests that the rejection of amended claim 1 as being anticipated by McCorkle Jr. under 35 U.S.C. §102 (b) be withdrawn.

Claims 6-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over McCorkle, Jr. in view of U.S. Patent No. 5,579,762 to Lee. Applicant traverses the rejection and submits that the Examiner has again failed to make a *prima facie* case of obviousness of Claims 6-9.

Lee teaches a hollow endotracheal device that comprises an adapter having longitudinal grooves. Figure 1. McCorkle Jr. and amended claim 1 are described above.

First, even when combined Waters and Lee fail to teach all of the limitations of Claim 1. Claims 6-9 depend from amended claim 1, and therefore incorporate all of the subject matter therein. Lee when combined with Waters does not teach or suggest all of the elements of amended claim 1, as discussed above. Therefore, for the same reasons expressed about is submitted that all of the limitations of claims 6-9 are not taught or suggested by Waters, alone, or in combination with Lee.

New claim 17 is submitted to be patentable for all of the reasons stated above.

Applicant believes that the arguments asserted and the amendments presented herein place all of the pending claims in condition for allowance. If the present amendments and arguments do not place the application in condition for allowance, the Examiner hereby requests

an interview with the Examiner. It is respectfully requested that the Examiner contact the Applicant's undersigned attorney by telephone at (314) 872-8118 to schedule an interview.

Respectfully submitted,

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